REMARKS

Regarding the Claim Amendments presented in this reply:

The amendments to the claims add no new matter. The amendment to claim 10, merely incorporates the subject matter of claims 15 and 16 into claim 10 in the alternative. Claim 22 has been amended to use the transitional phrase "consisting essentially of" instead of "comprising." Claims 25 – 28 have been canceled.

Regarding the Prosecution History:

Applicants filed an Appeal Brief on June 25, 2007. In the non-final Office action mailed November 01, 2007, the Examiner indicated that the arguments presented in the Appeal Brief filed, with respect to the rejection of claims 10 – 12, and 14 – 28 under 35 U.S.C §103(a) were persuasive. However, the Examiner rejected:

I. claims 25 – 28 under 35 U.S.C §112, second paragraph;
II. claims 10 – 12, 14, 17, 19, 20 and 22 – 27 under 35 U.S.C §102(b) over *Guzi, Jr. et al.* (US 4,127,422);
III. claims 10 and 18 under 35 U.S.C §103(a) over *Guzi et al.* (US 4,127,422);
IV. claims 10 – 12, 14 – 20, and 22 – 28 under 35 U.S.C §103(a) over *Guzi, Jr. et al.* (US 4,127,422) in view of *Staniforth et al.* (US 5,858,412) and *Zeligs et al.* (US 6,086,915); and
V. claims 10 and 21 under 35 U.S.C §103(a) over *Kolter et al.* (US 6,066,334).

Regarding Rejection I:

The Examiner should withdraw the rejection of claims 25 – 28 under 35 U.S.C §112, second paragraph. The cancellation of claims 25 – 28 renders this rejection moot.

Regarding Rejection II:

The Examiner should withdraw the rejection of claims 10 – 12, 14, 17, 19, 20 and 22 – 27 under 35 U.S.C §102(b) over *Guzi, Jr. et al.* (US 4,127,422). Applicants respectfully note that it is unclear why the Examiner makes this rejection after indicating that the remarks presented regarding the previous rejection of claims 10 – 12, 14, 17 – 27 under 35 U.S.C. §103(a) over *Ball et al.* (US 6,063,865) and *Guzi Jr. et al.* (US 4,127,422) were persuasive.

The Examiner has acknowledged that "[t]he [*Guzi Jr. et al.*] reference does not disclose the specific surfactant[s] [] of claims 15 or 16...."[1] Since, the amendment to claim 10, incorporates the subject matter of claims 15 and 16 into claim 10 in the alternative, the Examiner should agree that the *Guzi Jr. et al.* reference does not anticipate claim 10 or claims 11 – 12, 14 – 18 and 20 – 21, which depend therefrom.

Both claims 10 and 22, are directed to process for producing an excipient for use in solid pharmaceutical dosage forms wherein the excipient consists essentially of a pharmaceutically acceptable polymer, and a liquid or semisolid solubilizing surface-active substance. The *Guzi, Jr. et al.* pigment dispersion does not consist essentially of a pharmaceutically acceptable polymer, and a liquid or semisolid solubilizing surface-active substance. The *Guzi, Jr. et al.* reference "relates to dry pigment compositions in water-dispersible form...."[2] The reference explains that "[t]he invention can be practiced with the inorganic and organic prime pigments, extender pigments, metallic pigments, the various finely divided channel and furnace blacks and the like."[3] The reference indicates that the dry pigment compositions were evaluated for use in latex paint formulations,[4] and as a "colorant for paper coating compositions, disposable nonwovens, melamine formaldehyde laminates and aqueous flexographic ink vehicles...."[5] The reference describes typical pigments that are suitable for use in the dry pigment compositions,[6] but

[1] Page 5, lines 2 – 3 of the Office action mailed November 01, 2007.
[2] Column 1, indicated lines 10 – 11 of US 4,127,422.
[3] Column 2, indicated lines 59 – 62 of US 4,127,422.
[4] See Example 1, columns 5 and 6 of US 4,127,422.
[5] Column 7, lines 44 – 48 of US 4,127,422.
[6] See: Column 2, indicated line 62 – column 3, indicated line 2 of US 4,127,422.

stresses that "[i]t is of course understood and appreciated that all pigments do not behave in the same manner in a given system and that for each pigment there will be an optimum concentration."[7] *Guzi, Jr. et al.* emphasize that "[w]ithin the scope of the present invention it has been found that compositions containing high concentrations of pigment can be produced."

Accordingly, *Guzi, Jr. et al.* disclose a two step process comprising the steps of: forming a homogeneous mixture comprising milled or homogenized pigment, water, and … from 15 to 45% [by weight of the pigment] of a non-ionic dispersing agent … from 10 to about 67% [by weight of the pigment] of at least one water-dispersible nonionic polymer … and from 0 to about 40% [by weight of the pigment] of a nonionic colloid … and removing the water from said mixture until a dry composition is obtained … the total amount of dispersing agent, polymer and colloid being from 20 to 45% by weight of the dry composition.[8]

The following table illustrates possible compositions of *Guzi, Jr. et al.*'s dry pigment composition.

	Parts by weight of Dry Pigment Composition with Minimum Dispersing Agent (15% by weight of pigment)	Parts by weight of Dry Pigment Composition with Maximum Dispersing Agent (45 % by weight of pigment)
Pigment (parts by weight):	100	100
Dispersing (parts by weight):	15	45
Polymer (parts by weight):	67	10
Colloid (parts by weight):	0	0
Total (parts by weight):	182	155
Total amount of dispersing agent, polymer and colloid by weight of the dry composition (must be from 20 to 45%):	45%	35%
Amount of dispersing agent in the dry compositon	8%	29%

[7] Column 2, indicated line 10 – 13 of US 4,127,422.
[8] Column 2, indicated lines 26 – 44 of US 4,127,422 (emphasis added).

The table above illustrates that the weight percentages of pigment (from 15 to 45%) given for the amount of dispersing agent utilized in the process disclosed by the *Guzi, Jr. et al.* reference are not the minimum and maximum weight percentages of dispersing agent in the dry pigment composition that is produced by the process. Indeed, the *Guzi, Jr. et al.* reference is focused on ensuring that "[dry pigment] compositions containing high concentrations of pigment [are] produced…."[9] The *Guzi, Jr. et al.* reference teaches that despite the risk of detriment to other desirable properties a "sufficient [amount of] dispersing agent must be present to provide ease of processing and particle size reduction."[10] More specifically, the reference teaches that "[u]sually, an amount between about 15 and 35% [of dispersing agent] by weight of the pigment will provide good dispersibility without detriment to any other desirable properties."[11]

Guzi, Jr. et al. stress that "[t]he practice of the invention also requires the presence of from 10% to about 67% by weight of the pigment of a water-dispersible nonionic polymer which is either an at least partially hydrolyzed polymer of vinyl acetate, a polymer of an N-vinyl pyrrolidone or mixtures thereof."[12] *Guzi, Jr. et al.* make clear that "The function of the polymer is multiphase since it:

[1] acts synergistically with the dispersing agent to reduce the pigment particle size beyond that which can be accomplished by the dispersing agent alone,

[2] acts as a coating for the pigment particles to prevent reagglomeration during the drying process,

[3] acts to prevent flocculation and provides broad compatibility in a broad variety of aqueous systems."[13]

Applicants respectfully submit that anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention.[14] Thus, the reference does not anticipate independent claims 10 and 22. The reference does not anticipate dependent claims 11 – 12, 14 – 18, 20 – 21 which depend from claim 10, or dependent claims 23 – 24 which depend from claim 22. Claims 25 –

[9] Column 2, indicated lines 15 – 16 of US 4,127,422.
[10] Column 3, indicated lines 46 – 48 of US 4,127,422.
[11] Column 3, indicated lines 48 – 51 of US 4,127,422.
[12] Column 3, indicated lines 52 – 57 of US 4,127,422.
[13] Column 3, indicated lines 57 – 64 of US 4,127,422.
[14] *See, RCA Corp. v. Applied Digital Data Systems, Inc.,* 730 F.2d 1440, 1444 (Fed. Cir. 1984).

28 have been canceled.

For at least these reasons, it is respectfully submitted that the present rejection should be withdrawn.

Regarding Rejection III:

The Examiner should withdraw the rejection of claims 10 and 18 under 35 U.S.C §103(a) over *Guzi et al.* (US 4,127,422). Applicants respectfully note that it is unclear why the Examiner makes this rejection after indicating that the remarks presented regarding the previous rejection of claims 10 – 12, 14, 17 – 27 under 35 U.S.C. §103(a) over *Ball et al.* (US 6,063,865) and *Guzi Jr. et al.* (US 4,127,422) were persuasive. However, Applicants respectfully reemphasize the following remarks.

As discussed above, the Examiner has acknowledged that "[t]he [*Guzi Jr. et al.*] reference does not disclose the specific surfactant[s] [] of claims 15 or 16...."[15] Since, the amendment to claim 10, incorporates the subject matter of claims 15 and 16 into claim 10 in the alternative, the Examiner should agree that the *Guzi Jr. et al.* reference does not obviate claim 10 or claim 18, which depends therefrom.

Claim 10 is directed to a process for producing an excipient for use in solid pharmaceutical dosage forms. The *Guzi, Jr. et al.* reference does not disclose a process for producing an excipient adapted for use in a solid pharmaceutical dosage form. The *Guzi, Jr. et al.* reference is concerned with producing a pigment dispersion which comprises a pigment, and a non-ionic material which comprises a dispersing agent and a polymer. The *Guzi, Jr. et al.* reference is nonanalogous art and cannot be relied upon for purposes of 35 U.S.C §103, because it does not address a "need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue]."[16]

Claim 10 is directed to a process for producing an excipient for use in solid pharmaceutical dosage forms wherein the excipient consists essentially of a pharmaceutically acceptable polymer, and a liquid or semisolid solubilizing surface-

[15] Page 5, lines 2 – 3 of the Office action mailed November 01, 2007.
[16] KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007) (*See also* MPEP §2141.01(a)).

active substance. As expressed above, the *Guzi, Jr. et al.* pigment dispersion does not consist essentially of a pharmaceutically acceptable polymer, and a liquid or semisolid solubilizing surface-active substance. For at least these reasons, the *Guzi Jr. et al.* reference does not obviate claim 10 or claim 18, which depends therefrom.

For at least these reasons, it is respectfully submitted that the present rejection should be withdrawn.

Regarding Rejection IV:

The Examiner should withdraw the rejection of claims 10 – 12, 14 – 20, and 22 – 28 under 35 U.S.C §103(a) over *Guzi, Jr. et al.* (US 4,127,422) in view of *Staniforth et al.* (US 5,858,412) and *Zeligs et al.* (US 6,086,915).

It should be clear from the discussion above that even if the proposed combinations were made the resulting combination would not meet all of the claim limitations. Again, the *Guzi, Jr. et al.* reference does not disclose a process for producing an excipient adapted for use in a solid pharmaceutical dosage form. The *Guzi, Jr. et al.* reference is concerned with producing a pigment dispersion which comprises a pigment, and a non-ionic material which comprises a dispersing agent and a polymer. The *Guzi, Jr. et al.* reference is nonanalogous art and cannot be relied upon for purposes of 35 U.S.C §103, because it does not address a "need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue]."[17]

Furthermore, the *Guzi, Jr. et al.* pigment dispersion does not consist essentially of a pharmaceutically acceptable polymer, and a liquid or semisolid solubilizing surface-active substance. Thus, the reference does not obviate independent claims 10 and 22. The reference does not obviate dependent claims 11 – 12, 14 – 18, 20 – 21 which depend from claim 10, or dependent claims 23 – 24 which depend from claim 22. Claims 25 – 28 have been canceled.

Applicants respectfully note that the cited references provide no "apparent reason

[17] KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007) (*See also* MPEP §2141.01(a)).

to combine known elements in the fashion claimed ...."[18] First, referring to Column 11, lines 25 – 30 of the *Staniforth et al.* reference, the Examiner suggests that a skilled artisan would have found it obvious to modify *Guzi, Jr. et al.* by utilizing "an ethoxylated sorbitan fatty acid ester"[19] of the *Staniforth et al.* reference "to improve the compressibility of the resulting microparticles."[20] To the contrary, applicants respectfully submit that a skilled artisan would not have considered the *Staniforth et al.* reference as a helpful and proper basis for modification, because the *Guzi et al.* reference is concerned with producing pigment dispersion for paper coating and other technical applications (see col. 7, lines 45 – 52). The Examiner has not met the burden of demonstrating an apparent reason to make the proposed modifications with a reasonable expectation of success. Second, referring to Column 11, line 34 of the *Zeligs et al.* reference, the Examiner suggests that a skilled artisan would have found it obvious to modify *Guzi, Jr. et al.* by utilizing "castor oil derivatives"[21] of the *Zeligs et al.* reference "to improve the stability of the spray[-]dried particles ...."[22] To the contrary, applicants respectfully submit that a skilled artisan would not have considered the *Zeligs et al.* reference as a helpful and proper basis for modification, because the *Zeligs et al.* reference relates to the manufacture of compositions comprising hydrophobic phytochemical active ingredients. The Examiner has not met the burden of demonstrating an apparent reason to make the proposed modifications with a reasonable expectation of success.

For at least these reasons, it is respectfully submitted that the present rejection should be withdrawn.

Regarding Rejection V:

The Examiner should withdraw the rejection of claims 10 and 21 under 35 U.S.C §103(a) over *Kolter et al.* (US 6,066,334).

Making reference to the abstract and to column 3, lines 32 – 35 of the *Kolter et al.* reference, the Examiner states that the reference "discloses a redispersible microparticle

[18] *KSR Int'l v. Teleflex, Inc.,* 550 U.S. ___ (2007), Slip op. at 14, 127 S.Ct. 1727 at 1741.
[19] Page 5, line 7 of the Office action mailed November 01, 2007.
[20] Page 5, lines 11 – 12 of the Office action mailed November 01, 2007.
[21] Page 5, line 13 of the Office action mailed November 01, 2007.
[22] Page 5, line 18 of the Office action mailed November 01, 2007.

formulation comprising polyvinylpyrrolidone and up to 10% of a surfactant...." This portion of the reference merely states that "[e]mulsifiers which can be employed are both ionic and nonionic emulsifiers or mixtures thereof. Their total concentration is from 0.2 to 10% by weight, preferably from 0.4 to 7% by weight, based on the total monomer content."[23]

Independent claim 10, as amended, is directed to a process for producing an excipient adapted for use in a solid pharmaceutical dosage form, wherein the excipient consists essentially of a pharmaceutically acceptable polymer and a liquid or semisolid solubilizing surface-active substance, comprising ethoxylated sorbitan fatty acid esters, or the products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid. The present rejection is moot in light of the amendment to claim 10, because the rejection does not meet all of the claim limitations. Claim 21 depends from claim 10. For this reason, the rejection should be withdrawn.

For at least these reasons, it is respectfully submitted that the present rejection should be withdrawn.

In Conclusion:

The present application is in condition for allowance. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

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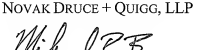

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[23] Column 3, lines 32 – 35 of US 6,066,334.